

IMPROVING REGULATORY TRANSPARENCY FOR NEW
MEDICAL THERAPIES ACT

JULY 29, 2014.—Ordered to be printed

Mr. UPTON, from the Committee on Energy and Commerce,
submitted the following

R E P O R T

[To accompany H.R. 4299]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 4299) to amend the Controlled Substances Act with respect to drug scheduling recommendations by the Secretary of Health and Human Services, and with respect to registration of manufacturers and distributors seeking to conduct clinical testing, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

CONTENTS

| | Page |
|---|------|
| Purpose and Summary | 2 |
| Background and Need for Legislation | 2 |
| Hearings | 3 |
| Committee Consideration | 3 |
| Committee Votes | 3 |
| Committee Oversight Findings | 3 |
| Statement of General Performance Goals and Objectives | 3 |
| New Budget Authority, Entitlement Authority, and Tax Expenditures | 3 |
| Earmark, Limited Tax Benefits, and Limited Tariff Benefits | 4 |
| Committee Cost Estimate | 4 |
| Congressional Budget Office Estimate | 4 |
| Federal Mandates Statement | 4 |
| Duplication of Federal Programs | 5 |
| Disclosure of Directed Rule Makings | 5 |
| Advisory Committee Statement | 5 |
| Applicability to Legislative Branch | 5 |
| Section-by-Section Analysis of the Legislation | 5 |
| Changes in Existing Law Made by the Bill, as Reported | 5 |

PURPOSE AND SUMMARY

The bill would amend the Controlled Substances Act (CSA) to require the Attorney General to issue an interim final rule placing a drug or substance that has not been marketed previously in the United States and that has abuse potential in the CSA schedule recommended by the Secretary of Health and Human Services (HHS) within 45 days of receiving such recommendation. If the drug or substance has been approved by the Food and Drug Administration (FDA), upon issuance of the interim final rule, marketing of the product is permitted, subject to the controls included in the schedule.

Under current law, if the Secretary of HHS recommends that a drug or substance be decontrolled, the Attorney General shall not control the drug or substance. The bill does not alter the Attorney General's ministerial obligation to carry out the Secretary's recommendation.

The bill also would amend the CSA to require the Attorney General, within 180 days of receiving an application for registration to manufacture or distribute a controlled substance that indicates the substance will be used only in connection with clinical trials, to make a final decision on whether to approve the application or provide notice to the applicant of the outstanding issues that must be resolved and an estimated date on which a final decision will be made. The bill does not force the Attorney General to make a decision, but brings transparency to the process.

BACKGROUND AND NEED FOR LEGISLATION

In addition to requiring approval by the FDA, drugs and substances that have not been marketed previously in the United States and that have abuse potential also must be scheduled under the CSA by the DEA before a company can begin marketing its product. In recent years, an increasing number of companies have had their product launches delayed because of lengthy and unpredictable review times associated with DEA scheduling decisions.

During FDA's approval process, the agency examines the abuse potential of the new drug and makes a scheduling recommendation through the Secretary of HHS to the DEA. In formulating its recommendations, the FDA uses an eight part test outlined in Section 201(c) of the CSA. Currently, the DEA also utilizes the eight part test, but FDA's decisions related to scientific and medical matters are binding on the DEA. Because of the binding nature of FDA's decisionmaking in these areas and due to the fact that DEA's primary examination typically involves post-market experience with the drug, over the past fifteen years, DEA has not made any scheduling decision for a new drug that was contrary to the FDA recommendation. H.R. 4299 would remove this duplicative DEA review process for new drugs and require DEA to take the ministerial step of issuing an interim final rule within 45 days of receiving FDA's scheduling recommendation so companies can begin marketing their product if it has been approved by FDA, and patients can have access to the new therapy. The DEA would retain its authority to transfer the drug between schedules under Section 201 of the CSA.

Inconsistency and lengthy review times at DEA are not limited to scheduling decisions for new drugs, but also apply to the review of registration applications submitted by companies in advance of conducting clinical trials. The DEA registration does not distinguish between the manufacturing of a controlled substance for marketing and the manufacturing of a controlled substance for the use in clinical trials. There is no timetable for the DEA to grant approval of registration applications, and there is no process for the applicant to determine the reasons for a delay in the application. H.R. 4299 would bring transparency and predictability to the registration process so companies can properly plan clinical trial schedules for new therapies.

HEARINGS

The Committee on Energy and Commerce held a hearing on April 7, 2014.

COMMITTEE CONSIDERATION

On May 28, 2014, the Subcommittee on Health met in open markup session and approved H.R. 4299, Improving Regulatory Transparency for New Medical Therapies Act, for full Committee consideration by a voice vote. On June 10, 2014, the full Committee met in open markup session and approved H.R. 4299 by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering H.R. 4299. A motion by Mr. Upton to order H.R. 4299 reported to the House, without amendment, was agreed to by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee held a hearing and made findings that are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The objective of this legislation is to facilitate patient access to new therapies in an efficient and transparent manner, while ensuring appropriate controls are in place under the CSA.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 4299 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

In compliance with clause 9(e), 9(f), and 9(g) of rule XXI of the Rules of the House of Representatives, the Committee finds that H.R. 4299 contains no earmarks, limited tax benefits, or limited tariff benefits.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

JUNE 26, 2014.

Hon. FRED UPTON,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 4299, the Improving Regulatory Transparency for New Medical Therapies Act.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Mark Grabowicz.

Sincerely,

DOUGLAS W. ELMENDORF.

Enclosure.

H.R. 4299—Improving Regulatory Transparency for New Medical Therapies Act

H.R. 4299 would modify the administrative procedures followed by the Department of Justice in regulating new drugs that are already approved by the Food and Drug Administration and in authorizing drugs to be used in clinical trials. The legislation would aim to streamline the current review and approval process. CBO estimates that implementing the bill would have no significant costs to the federal government. Enacting the legislation would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply.

H.R. 4299 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would impose no costs on state, local, or tribal governments.

The CBO staff contact for this estimate is Mark Grabowicz. The estimate was approved by Theresa Gullo, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

DUPLICATION OF FEDERAL PROGRAMS

No provision of H.R. 4299 establishes or reauthorizes a program of the Federal Government known to be duplicative of another Federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

DISCLOSURE OF DIRECTED RULE MAKINGS

The Committee estimates that enacting H.R. 4299 specifically directs to be completed zero specific rule makings within the meaning of 5 U.S.C. 551.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1: Short title

Section 1 provides the short title of “Improving Regulatory Transparency for New Medical Therapies Act.”

Section 2: Scheduling of substances included in new FDA-approved drugs

Section 2 amends Section 201 of the CSA (21 U.S.C. 811) by requiring DEA to issue an interim final rule within 45 days of receiving FDA’s recommendation and place the drug or substance on the recommended schedule.

Section 3: Enhancing new drug development

Section 3 amends Section 302 of the CSA by requiring DEA, within 180 days of receiving such an application, to make a determination on a registration application that includes an indication that the controlled substance will be used only in connection with clinical trials, or to provide notice to the applicant of the outstanding issues that must be resolved along with an estimated date on which a final decision on the application will be made.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italic and existing law in which no change is proposed is shown in roman):

CONTROLLED SUBSTANCES ACT

TITLE II—CONTROL AND ENFORCEMENT

* * * * *

PART B—AUTHORITY TO CONTROL; STANDARDS AND SCHEDULES

AUTHORITY AND CRITERIA FOR CLASSIFICATION OF SUBSTANCES

SEC. 201. (a) * * *

* * * * *

(i) Within 45 days of receiving a recommendation from the Secretary to add a drug or substance that has never been marketed in the United States to a schedule under this title, the Attorney General shall, without regard to the findings required by subsection (a) of this section or section 202(b), issue an interim final rule, under the exception for good cause described in subparagraph (B) of section 553(b) of title 5, United States Code, placing the drug or substance into the schedule recommended by the Secretary. The interim final rule shall be made immediately effective under section 553(d)(3) of title 5, United States Code.

* * * * *

PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES; PIPERIDINE REPORTING

* * * * *

PERSONS REQUIRED TO REGISTER

SEC. 302. (a) * * *

* * * * *

(h)(1) A person who submits an application for registration to manufacture or distribute a controlled substance in accordance with this section may indicate on the registration application that the substance will be used only in connection with clinical trials of a drug in accordance with section 505(i) of the Federal Food, Drug, and Cosmetic Act.

(2) When an application for registration to manufacture or distribute a controlled substance includes an indication that the controlled substance will be used only in connection with clinical trials of a drug in accordance with section 505(i) of the Federal Food, Drug, and Cosmetic Act, the Attorney General shall—

(A) make a final decision on the application for registration within 180 days; or

(B) provide notice to the applicant in writing of—

(i) the outstanding issues that must be resolved in order to reach a final decision on the application; and

(ii) the estimated date on which a final decision on the application will be made.

* * * * *